Applying the Federal Regulations When the Proposed Research Involves the Use of Existing Data
(Existing means available prior to initiation of the research)

Research Examples	**Determination of CDC's Role**
CDC employee uses data obtained from dead individuals (individuals are dead at the time the data are collected) Requirements for review: protocol	Not engaged in human subjects research
CDC employee uses data that are unidentified Requirements for review: protocol	Not engaged in human subjects research
CDC employee uses unlinked data:	
Data are unlinked by repository (repository is not a collaborator)	Not engaged in human subjects research
Data are unlinked by repository (repository is a collaborator)	Exempt
Data are unlinked by clinic staff (clinic staff are not collaborators)	Not engaged in human subjects research
Data are unlinked by clinic staff (clinic staff are collaborators)	Exempt
Data are unlinked by CDC or any study investigator	Exempt
Data are linked temporarily and then unlinked	IRB Review
Requirements for review: protocol and consent form, if data are from previous research. Protocol should contain a description of methods for delinking data and a statement that there is not harm to participants by delinking the data (e.g., the results will not have clinical significance).	

Research Examples	**Determination of CDC's Role**
CDC employee uses identified data that are publicly available (means to public)	Exempt
Requirements for review: protocol	
CDC employee uses identified or coded data:	
CDC employee releases identifiable data or permits investigators to obtain identifiable data without subjects' explicit written permission	IRB Review
Requirements for review: protocol and consent form, if data are from previous research	
CDC employee releases identifiable data with subjects' explicit written permission	Not engaged in human subjects research
Requirements for review: protocol and consent form if data are from previous research	
CDC employee releases identifiable data to state health departments for legitimate public health purposes	Not engaged in human subjects research
Requirements for review: CIO specific	
State health departments that use identifiable data for research purposes	IRB Review
Requirements for review: N/A	
CDC employee obtains, receives or possesses identifiable data for research purposes	IRB Review
Requirements for review: protocol and consent form if data are from previous research	

Research Examples	**Determination of CDC's Role**
CDC employee receives identifiable data from an institution with an OPRR-approved assurance and there is a written agreement unequivocally prohibiting release of identifying information to recipient investigators Requirements for review: protocol, consent form, if data are from previous research, institution's assurance number and copy of IRB approval letter, and copy of written agreement	Not engaged in human subjects research
CDC employee acting as consultant but at no time obtains, receives, or possesses identifiable data Requirements for review: protocol and consent form, if data are from previous research	Not engaged in human subjects research
CDC employee acting as consultant and accesses identifiable data at collaborator's institution, employee's falls under collaborator's IRB Requirements for review: protocol and consent form, if data are from previous research	Not engaged in human subjects research
CDC employee acting as consultant obtains identifiable data at own institution Requirements for review: protocol and consent form, if data are from previous research	IRB review
CDC performs commercial services (meriting neither professional recognition nor publication privileges) and adheres to commonly recognized professional standards Requirements for review: CIO specific	Not engaged in human subjects research

NOTES:

OPRR requires that a third party make the determination that a study involving existing data is not human subjects research, is exempt, or requires IRB review. Generally, the third party is an IRB. At CDC, authority for determinations regarding whether an activity is research and involves human subjects is delegated to the CIOs. Exemption determinations are made by the Human Subjects Office.

OPRR-approved assurance means any type of OPRR assurance: MPA, SPA, or CPA. Explicit written consent means consent for release for the specific research study.

Definitions:

Original data can be generated in one of two forms:

Unidentified data (anonymous) are data for which identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved. Specimens and survey data can be collected in such a manner as to be considered unidentified.

Identified data are data that are linked to personal information in such a way that the person from whom the information was obtained could be identified by name, patient number, clear pedigree location, or by a combination of demographic information. Specimen and survey data can be collected in such a manner as to be considered identified. Medical records, school records, employment records, for example, are identified data when originally collected.

Data used from these two forms of original data can be classified in four ways with respect to identifiability:

Unidentified data (anonymous). Investigators obtain these data from a data set where the data are unidentified.

Unlinked data (anonymized). Investigators obtain these data from a data set or repository where the data are identified but prior to obtaining the data, the identifiers or codes are removed and there no link back to the original data.

Coded data (linked or identifiable). Investigators obtain these data from a data set or repository where the data are identified. Investigators obtain the data with a code rather than with personally identifying information such as a name.

Identified data. Investigators obtain these data with a personal identifier that would allow the investigators to link the data directly to the individual from whom the information was obtained.